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DATE MAILED: 01/05/2004

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|------------------------|------------------|
| 09/891,715 | 06/26/2001 | Richard L. Mueller | 5756-0013.30 | 1828 |
| 7590 01/05/2004 | | | EXAMINER | |
| PENNIE &EDMONDS LLP | | | RODRIGUEZ, CRIS LOIREN | |
| 1155 AVENUE OF THE AMERICAS NEW YORK, NY 10036 | | | ART UNIT | PAPER NUMBER |
| | | | 3763 | |

Please find below and/or attached an Office communication concerning this application or proceeding.

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|---|---|---|---|
| | Application No. | Applicant(s) | ئ |
| | 09/891,715 | MUELLER ET AL. | |
| Office Action Summary | Examin r | Art Unit | |
| | Cris L. Rodriguez | 3763 | |
| The MAILING DATE of this communica Period for Reply | tion appears on the cov r sh t w | ith the correspondence addr ss | |
| A SHORTENED STATUTORY PERIOD FOR THE MAILING DATE OF THIS COMMUNICA - Extensions of time may be available under the provisions of 3 after SIX (6) MONTHS from the mailing date of this communical of the period for reply specified above is less than thirty (30) of the No period for reply is specified above, the maximum statute Failure to reply within the set or extended period for reply will Any reply received by the Office later than three months after earned patent term adjustment. See 37 CFR 1.704(b). Status | ATION. 17 CFR 1.136(a). In no event, however, may a cation. ays, a reply within the statutory minimum of thiony period will apply and will expire SIX (6) MOI by statute, cause the application to become A | reply be timely filed ty (30) days will be considered timely. NTHS from the mailing date of this communication. BANDONED (35 U.S.C. § 133). | |
| 1) Responsive to communication(s) filed | on <u>20 O<i>ctober</i> 2003</u> . | | |
| 2a)⊠ This action is FINAL . 2b)[| This action is non-final. | | |
| 3) Since this application is in condition for closed in accordance with the practice | | | |
| Disposition of Claims | | | |
| 4) ⊠ Claim(s) 1-21 is/are pending in the app 4a) Of the above claim(s) 2-4,7-9,13-16 5) □ Claim(s) is/are allowed. 6) ⊠ Claim(s) 1,5,6,10-12,17,18 is/are rejection 7) □ Claim(s) is/are objected to. 8) □ Claim(s) are subject to restriction | <u>6 and 19-21</u> is/are withdrawn fron ted. | n consideration. | |
| Application Papers | ··· •·· •· •· •· •· • • • • • • • • • • | | |
| 9) The specification is objected to by the E | Evaminer | | |
| 10) The drawing(s) filed on is/are: a | | by the Examiner. | |
| Applicant may not request that any objection | on to the drawing(s) be held in abeya | nce. See 37 CFR 1.85(a). | |
| Replacement drawing sheet(s) including th | | | |
| 11)☐ The oath or declaration is objected to b | y the Examiner. Note the attache | d Office Action or form PTO-152. | |
| Priority under 35 U.S.C. §§ 119 and 120 | | | |
| 12) Acknowledgment is made of a claim for a) All b) Some * c) None of: 1. Certified copies of the priority do 2. Certified copies of the priority do 3. Copies of the certified copies of application from the Internationa * See the attached detailed Office action for since a specific reference was included in 37 CFR 1.78. a) The translation of the foreign languated acknowledgment is made of a claim for reference was included in the first senter | cuments have been received. cuments have been received in A the priority documents have beer I Bureau (PCT Rule 17.2(a)). or a list of the certified copies not domestic priority under 35 U.S.C n the first sentence of the specific lage provisional application has b domestic priority under 35 U.S.C | Application No In received in this National Stage received. § 119(e) (to a provisional application) cation or in an Application Data Sheet. seen received. §§ 120 and/or 121 since a specific | |
| Attachment(s) | <u></u> | | |
| Notice of References Cited (PTO-892) Notice of Draftsperson's Patent Drawing Review (PTO 3) Information Disclosure Statement(s) (PTO-1449) Paper | -948) 5) Notice of | Summary (PTO-413) Paper No(s) Informal Patent Application (PTO-152) | |

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DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
- 2. Claims 1, 5, 6, 10-12 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Edwards et al (US 5,536,267).
 - Edwards discloses a device having a shaft 12, a control structure 18, at least one injury effector and at least one therapeutic-substance delivery effector at the distal end of the shaft by means of element 22 and spaced from one another.

 The device is capable of treating ischemic tissue.
- 3. Claims 1, 5, 6, 10, 11, 17, and 18 are rejected under 35 U.S.C. 102(e) as being anticipated by Hofmann (US 6,241,701).

Hofmann discloses a device (figs. 1-3, 8-9b, 18a-18b, but better seen in figs. 18a-18b) and having a shaft 1810, a control structure 1812 to be connected to the instrument control, at least one injury effector and at least one therapeutic-substance delivery effector at 1822 at the distal end of the shaft. The device is capable of treating ischemic tissue.

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Response to Arguments

4. Applicant's arguments filed October 20, 2003 have been fully considered but they are not persuasive.

In response to applicant's argument that neither Edwards nor Hofmann teaches the treatment of ischemic tissue to promote blood vessel growth and tissue regeneration, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

Conclusion

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cris L. Rodriguez whose telephone number is (703) 308-2194. The examiner can normally be reached on 7:30 am - 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (703) 308-3552. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

December 29, 2003

Cris L. Ródriguez

Examiner . Art Unit 3763

BRIAN L. CASLER
SUPTOVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700